OCT 3 - 2008

K081799

510(k) SUMMARY

A. Device Name **GORE Tri-Lobe Balloon Catheter**

Proprietary Name:	GORE Tri-Lobe Balloon Catheter
Common Name:	Balloon Catheter
Classification Name:	Catheter, Percutaneous
Product Code:	DQY
21 CFR:	870.1250
Device Class:	Class II

B. Intended Use

The GORE Tri-Lobe Balloon Catheter is intended to assist in the dilatation of self-expanding endoprostheses in large diameter vessels.

C. Device Description

The next generation GORE Tri-Lobe Balloon Catheter is designed to be used in conjunction with the implantation of an endoprosthesis. The triangular arrangement of balloons allows for continuous blood flow through the implanted device during inflation of the balloon. The next generation GORE Tri-Lobe Balloon Catheter is available in two balloon sizes.

D. Principle of Operation and Technology

The three individual balloons apply pressure to the implanted endoprostheses and facilitate improved proximal and distal wall apposition of the implanted endoprostheses.

E. Materials

The GORE Tri-Lobe Balloon Catheter is composed of a Pebax catheter with a polycarbonate hub, polyurethane balloons, platinum iridium marker bands, and a distal tip with barium sulphate.

F. Performance

A comparison of the next generation balloon catheter and predicate devices show that the technological characteristics such as product performance, design and intended use are substantially equivalent to the currently marketed predicate devices. *In vitro* bench testing performance evaluations demonstrated that the next generation GORE Tri-Lobe Balloon Catheter met the acceptance criteria and that its performance was comparable to the predicate devices. No new safety or effectiveness issues were raised during the testing,

and, therefore, the GORE Tri-Lobe Balloon Catheter may be considered substantially equivalent to the predicate devices.

G. Substantial Equivalence

The next generation GORE Tri-Lobe Balloon Catheter is substantially equivalent to the following predicate devices:

- GORE Tri-Lobe Balloon Catheter (W. L. GORE & Associates, Flagstaff, AZ) – K033670
- Reliant Stent Graft Balloon Catheter (Medtronic Endovascular Innovations, CA) - K050038
- Cook CODA Balloon Catheter (Cook, Inc., Bloomington, IN) – K032869
- Equalizer™ Balloon Catheter (Boston Scientific Corporation, Natick, MA) – K021721

Differences between the devices do not raise any significant issues of safety or effectiveness.

W. L. GORE & Associates, Inc. statement of substantial equivalence is done solely to comply with the requirements of the Federal Food, Drug and Cosmetic Act and is not intended whatsoever to be the basis for a patent infringement action.

Date Prepared: June 24, 2008

Prepared By:

Kanu H. Vadodaria, M.S., RAC
Regulatory Affairs Associate
W. L. GORE & Associates, Inc.
Medical Products Division
3450 West Kiltie Lane
Flagstaff, Arizona 86001
Phone: 928-864-4259
Fax: 928-864-4304
E-mail: *kvadodar@wlGORE.com*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 3 - 2008

W. L. Gore & Associates, Inc.
c/o Mr. Kanu Vadodaria
3450 West Kiltie Lane
Flagstaff, AZ 86001

Re: K081799
Trade/Device Name: Gore Tri-Lobe Balloon Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: September 15, 2008
Received: September 17, 2008

Dear Mr. Vadodaria:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K081799

Device Name: GORE Tri-Lobe Balloon Catheter

Indications For Use:

The GORE Tri-Lobe Balloon Catheter is intended to assist in the dilatation of self expanding endoprostheses in large diameter vessels.

Prescription Use ___X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K081799